DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 20, 2015

Biomet Manufacturing Corporation
Mr. Adam Cargill
Regulatory Affairs Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K143037
Trade/Device Name: SnapShot Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: October 20, 2014
Received: October 22, 2014

Dear Mr. Cargill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143037

Device Name
SnapShot Fixation System

Indications for Use *(Describe)*
The SnapShot Fixation System is indicated for use in soft tissue reattachment procedures in the following shoulder procedures:

Bankart repair, SLAP repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

The SnapShot Fixation System is also indicated for supplementary fixation when used in conjunction with a primary fixation device in surgical procedures requiring graft fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BIOMET

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the SnapShot Fixation System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Office: 574-267-6639
Main Fax: 574-267-8137
Establishment Registration Number: 1825034

Contact: Adam Cargill
Regulatory Affairs Specialist, Sports Medicine

Date: January 16, 2015

Subject Device: Trade Name: SnapShot Fixation System

Common Name: Soft Tissue Fixation Device

Classification Name: JDR - Staple, Fixation, Bone (21 CFR 888.3030)

Legally marketed devices to which substantial equivalence is claimed:

Biomet Lactosorb Pop Rivet (K981798)
Biomet PEEK Knotless Anchor (K070389) – reference for materials

Device Description

The SnapShot Fixation System consists of a SnapShot implant and deployment gun. The SnapShot implant is a PEEK rivet comprised of two components, a cannulated body and a bullet. The SnapShot deployment gun comes packaged pre-loaded with the SnapShot implant and is designed to ease insertion of the SnapShot implant into the bone hole. A reusable deployment gun and reusable drill are also available and can be used with the implant reloads.

Intended Use and Indications for Use

The SnapShot Fixation System is indicated for use in soft tissue reattachment procedures in the following shoulder procedures:

Bankart repair, SLAP repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

The SnapShot Fixation System is also indicated for supplementary fixation when used in conjunction with a primary fixation device in surgical procedures requiring graft fixation.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the SnapShot Fixation System are similar or identical to the predicate device or other previously cleared devices.

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The proposed SnapShot Fixation System has the same intended use as the predicate Lactosorb Pop Rivet (K981798) for soft tissue to bone fixation.
- **Indications for Use:** The proposed SnapShot Fixation System has similar indications for use as the predicate Lactosorb Pop Rivet (K981798), for soft tissue to bone fixation, with the addition of providing supplementary fixation in surgical procedures requiring graft fixation.
- **Materials:** The proposed SnapShot Fixation System utilizes the same implant material, polyetheretherketone (PEEK), as the PEEK Knotless Anchor (K070389).
- **Design Features:** The proposed SnapShot Fixation System has the same design features and is dimensionally similar to the predicate Lactosorb Pop Rivet (K981798).

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
    - Non-clinical laboratory testing was performed to verify the fixation strength of the SnapShot Fixation System in mechanical pullout testing as compared to the predicate LactoSorb Pop Rivet (K981798) for specific indications for use. The average pullout strength of the SnapShot Fixation System implants was statistically equivalent to or greater than that of the Lactosorb Pop Rivet. When testing supplemental fixation using a resorbable interference screw for primary fixation, the average pullout strength of the construct utilizing the SnapShot Fixation System for supplementary fixation was statistically greater than the construct with no supplemental fixation.

- Clinical Tests
    - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The proposed SnapShot Fixation System has similar intended use, technological characteristics, and mechanical performance as the Lactosorb Pop Rivet (K981798). The performance testing data identified no new risks and substantial equivalence to the legally marketed predicate device.